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EXAMINER

LUNDGREN, J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

DATE MAILED:

01/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/527,440

Applicant(s)

NAKAE ET AL.

Examiner

Jeffrey Lundgren

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-8, 11, and 19 are pending; claims 9, 10, and 12-19 have been cancelled. Claims 1-8, 11, and 19 will be examined on the merit.

### ***Claim Objections***

2. The objection to claims 1 in the Office Action mailed June 21, 2000, is overcome by means of Applicants' amendments in the response received October 23, 2000.

### ***New Grounds of Claim Objections***

3. The spacing of the claims is improper because the lines are crowded too closely together, making reading and entry of amendments difficult. Any further amendments to the claims submitted by Applicants, should be filed with lines one and one-half or double spaced on good quality paper are required. See 37 CFR 1.52(b).

### ***Claim Rejections - 35 USC § 112***

4. The rejections of claims 3-5 under 35 U.S.C. § 112, second paragraph, in the Office Action mailed June 21, 2000, is overcome by means of Applicants' amendments in the response received October 23, 2000.

### ***New Grounds of Rejection- 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-8, 11, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8, 11, and 19 are indefinite for reciting the term "a mutually different plurality" as the skilled artisan would not reasonably be able to determine what the plurality is mutually different than. For example, if a first set consists of elements A, B, and C, and a second set consists of elements D, E, and F, it is clear that each of the elements of either set are different, thus the plurality of sets (i.e., a first *and* second sets) are considered mutually different/exclusive between each set. However, there is no other plurality that Applicants are claiming such that the skilled artisan would have a reference point to determine how the plurality could possibly be mutually different. Correction is required.

Claims 1-8, 11, and 19 are indefinite for reciting the phrase "mutually different" to describe the: 1) DNA nucleotide sequences (line 2); and 2) partial sequences (line 14), as it is unclear how a mutually different plurality of DNA sequences can be "mutually different". For example, if a first set consists of elements A, B, and C, and a second set consists of elements D, E, and F, it is clear that each of the elements of either set are different, thus the plurality of sets (i.e., a first *and* second sets) are considered mutually different. However, it is not clear how a sequence of nucleotides (a nucleotide string consisting of 4 base types), is considered to be "mutually different" from any other nucleotide sequence. It would appear that DNA sequence are quite simply either different or the same. Applicants recitation of the term "mutually different" as it defines the DNAs on page 6, line 10 of the specification does not render this term definite. Correction is required.

Claims 1-8, 11, and 19 recite the limitation "the plurality of DNA nucleotide sequences"; for example, see line 8 of claim 1. There is insufficient antecedent basis for this limitation in the claim. The recitation of the term "the plurality of *mutually different* DNA nucleotide sequences" does not serve as proper antecedent basis for this limitation. Correction is required.

Claims 1, 7, 8, and 19 are indefinite for reciting the phrase "...conditions of each partial sequence's absence in DNA nucleotide sequences other than the DNA nucleotide sequence from which said each partial sequence is extracted", as the skilled artisan would not reasonably be able to determine the metes and bounds of this limitation. For example, in claim 1, starting on line 10, this is a step of determining, however, it is not clear how *conditions* pertaining to an *absence* are in any way determined, or what is determined about this particular condition.

Claims 1, 7, 8, and 11 recite the limitation "the positions" in reference to the plurality of partial sequences. There is insufficient antecedent basis for this limitation in the claim.

Claims 1, 7, 8, and 11, recite the limitation "the results" in the means for selecting. There is insufficient antecedent basis for this limitation in the claim.

Claims 1, 7, 8, and 19, are indefinite for reciting "amplifying said pair of primers to a plurality of hybridized DNA nucleotide sequence", as it is not clear how the *primers* are being *amplified* to the hybridized DNA. Clarification and/or correction is required.

Claims 1, 7, 11, and 19 are indefinite for reciting the phrase "automatically collated with genetic functions", as a processing step carried out by the processing means in the primer design system. The skilled artisan would not reasonably be able to determine the metes and bounds of this limitation. For example, if a primer is designed to specifically target and copy a particular gene (or region thereof), wherein said gene has been assigned a "genetic function", then it is not clear how a genetic function is assigned from the source of extraction. If the primer is designed to target and amplify a gene whose genetic function is unknown prior to amplification, then it is not clear how Applicant determine the genetic function in this final step. Correction is required.

Claim 1, 7, 8, and 19, recite the limitation "from which they are extracted". There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the range" in line 2 as it refers to an extent of GC content. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 and 7 are indefinite for reciting the phrase "based on" as a means of establishing a relationship between the plurality of DNA nucleotide sequences and the

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data. The skilled artisan would not reasonably be able to determine the metes and bounds of this limitation, as neither the claim nor specification reasonably set forth a "basis" for the skilled artisan. Applicants can overcome this rejection by replacing the phrase "based on" with the term "from".

Claim 11 is indefinite for reciting the phrase "obtained above", as a means of referring to the previously established nucleotide sequence data. Deletion of the phrase would overcome this rejection.

***Claim Rejections - 35 USC § 101***

7. The rejection of claims 9 and 10 under 35 U.S.C. 101 is withdrawn in view of Applicants' cancellation of the claims.

***Claim Rejections - 35 USC § 102***

8. The rejection of claims 1-8 under 35 U.S.C. 102(b) as being anticipated by Sninski *et al* (U.S. Patent 5,176,995, January 5, 1993), in the Office Action mailed on July 5, 2000, is overcome by means of Applicants' amendments in the response received on October 23, 2000.

9. The rejection of claims 1, 4, 7, and 11 under 35 U.S.C. 102(b) as being anticipated by Kariko *et al* (BioTechniques 18(6), 1048-1049, 1995), in the Office Action mailed on July 5, 2000, is overcome by means of Applicants' amendments in the response received on October 23, 2000.

***New Grounds of Rejection - 35 USC § 102***

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10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-8, 11, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowe et al (Nucleic Acids Research 18(7), 1757-1761, **1990**).

Claims 1-8, 11, and 19 are drawn to a method and system for designing primers, wherein the system has a means for selecting a *mutually different plurality of mutually different DNA nucleotide sequences* (i.e. different primers) from a database of nucleotide sequences, wherein a plurality of partial sequences are determined from the "plurality of DNA nucleotide sequences", the plurality of partial sequences meeting predetermined nucleotide criteria. The selection criteria may include a GC content range and/or a T<sub>m</sub> determination.

Lowe discloses of a computer program which rapidly scans nucleic acid sequences to select possible pairs of oligonucleotides suitable for use as primers to direct efficient DNA amplification by PCR methods (i.e., amplification of the target sequence onto the primer sequence). The program has a set of selection criteria which includes both the length of the sense and antisense primer, a GC-content range selection, a specified target sequence length (i.e., a "distance" determination), a selection criteria wherein the primer contains no more than four contiguous base pairs of homology to itself or its respective counterpart, and a predetermine T<sub>m</sub> selection (see *Primer Selection Algorithm*). The primer nucleotide sequences are selected from a target nucleotide sequence database, wherein the target nucleotide database can be provided by the users own experimental results saved in a computer readable format, or may be accessed through a compatible computer format in a commercial database, both of which may be read into a memory means for further processing/computation (see *Computer Algorithm*). Lowe provides two examples of their computer-based method and system for generating a plurality of different, high-specificity primers which

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meet a set of criteria defining the primers to be used for amplifying a target nucleic acid to the human Manganous superoxide dimutase gene and human retinoblastoma susceptibility gene (see page 1760, and Table II). Furthermore, following amplification reactions using the "designer" primers, and the target nucleic acid were experimentally confirmed through diagnostic means (i.e., collating genetic function; see *Discussion*).

### ***Claim Rejections - 35 USC § 103***

12. The rejection of claims 1-8, and 11 under 35 U.S.C. 103(a) as being unpatentable over Kariko *et al* (BioTechniques 18(6), 1048-1049, 1995) in view of Sninski *et al* (U.S. Patent 5,176,995, January 5, 1993), ), in the Office Action mailed on July 5, 2000, is overcome by means of Applicants' amendments in the response received on October 23, 2000.

### ***Conclusion***

13. No claims are allowable.

14. Any inquiry concerning the *merits* of this communication or earlier communications from the Examiner should be directed to Jeffrey S. Lundgren, whose telephone number is (703) 306-3221. The Examiner can normally be reached on Monday-Friday from 7:00 AM to 5:00 PM (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Michael Woodward, can be reached at (703) 308-4028.

Any inquiries of a *general* nature relating to this application should be directed to Ms. Pauline Farrier, Patent Analyst for Art Unit 1631, whose telephone number is (703) 305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1631 using (703) 308-0294. Please notify the



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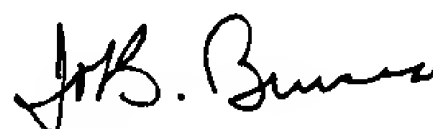
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Examiner of incoming facsimiles prior to sending papers to the aforementioned fax number. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).



Jeffrey S. Lundgren, Ph.D.



JOHN S. BRUSCA, PH.D.  
PRIMARY EXAMINER